K091528

Pride Mobility Products Corp.

Research & Development
182 Susquehanna Ave
Exeter, PA 18643
570-655-5574
FAX 655-2990
www.pridemobility.com

DEC - 2 2009

Exhibit 1

510(k) Summary
Pride Mobility Products Corporation
T3 Lift Chair

Submitter's Name & Address:
Pride Mobility Products Corporation
182 Susquehanna Avenue
Exeter, Pa. 18643
Phone: (570) 655-5574
Facsimile: (570) 655-2990

Contact Person:
Thomas Schappert
Official Correspondent

Date Prepared:
05-08-09

Name of Device and Proprietary Name:
T3 Lift Chair / Pride Mobility Products Corporation

Common or Usual Name:
Electric Lift Chair

Classification Name:
Electric Positioning Chair per 21 CFR, 890.3110

Product Code:
INO

Comparison to Predicate Devices:
The **T3 Lift Chair** is substantially equivalent to the Pride Mobility C5 (K070950) when comparing construction and performance. The performance characteristics and positioning of components are similar to achieve the same Intended Use. The T3 offers a dual actuator system vrs. one actuator on the C5; the dual actuator system enables the chair components to move independently to create additional comfort positioning.

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Device Description:
The Pride Mobility **T3 Lift Chair** is an upholstered chair having welded steel frame construction. The chair upholstery (foam and fabric) are compliant to Cal 117 and BS5852 Flammability requirements. The upholstered chair is assembled to a welded-steel lifting frame mechanism, and a Hand Control Switch Device engages motor / actuators to position the chair to recline, sitting, or standing positions. The system is a low voltage DC motor system that reduces the standard household alternating current of 110V AC / 240V AC to direct current (24 / 39V DC). The electrical components include the external transformer with battery backup, two motor / actuators, and the Hand Control.

Intended Use:
The Intended Use of the Pride Mobility **T3 Lift Chair** is to provide lift assistance for persons who have difficulty rising from a seated position to a standing position.

Non-Clinical Testing:
The Pride Mobility **T3 Lift Chair** was tested to the following Safety Standards:
CAL 117 Sections A, D, & E - Flammability Testing for Upholstered Furniture
BS5852 – Flammability (foam and fabric)
EN 61000-6-3, and EN 61000-6-1 – Electromagnetic Emissions & Immunity Tests
EN60601-1 / A2: 1995 / EN60601-1 / A2: 1995 – Medical Electrical Equipment – General Requirements for Safety
Fatigue Testing – Cycle Tests, Impact Tests, and Downward Force Tests

Discussion of Clinical Testing Performed:
N/A

Conclusions:
The Pride Mobility **T3 Lift Chair** has the same intended use and similar technological characteristics as the C5 (K070950), moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **T3 Lift Chair** is substantially equivalent to the predicate device, has passed all the necessary testing, and is considered to be safe for user operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Pride Mobility Products Corporation
% Mr. Thomas Schappert
182 Susquehanna Avenue
Exeter, Pennsylvania 18643-2694

DEC - 2 2009

Re: K091578
Trade/Device Name: T3/Electric Positioning Chair
Regulation Number: 21 CFR 890.3110
Regulation Name: Electric positioning chair
Regulatory Class: Class II
Product Code: INO
Dated: October 21, 2009
Received: November 2, 2009

Dear Mr. Schappert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 3

Indications for Use

510(k) Number (if known): K

Device Name: T3 / Electric Positioning Chair

Indications for Use:

The Intended Use of the Pride Mobility **T3 Lift Chair** is to provide lift assistance for persons who have difficulty rising from a seated position to a standing position.

Prescription Use__X__ AND / OR Over-The-Counter Use__X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091578